The National Cancer Institute

Intramural Review Process

U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES
Public Health Service
National Institutes of Health

The National Cancer Institute

Intramural Review Process

Prepared by

Management Analysis Branch
Office of the Director, NCI

For Administrative Use Only

U.S. DEPARTMENT
OF HEALTH AND
HUMAN SERVICES
Public Health Service
National Institutes of Health

Table of Contents

Foreword

Science is changing at an ever increasing pace and rapid changes require a willingness on the part of the scientific community to exchange new for old ideas. This is best accomplished through a system of review by scientific peers. We, and the community we serve, must be assured that we are supporting only the highest quality science in our intramural, as well as extramural, programs. Because our intramural programs are government laboratory facilities, they are by necessity operated differently than laboratories and clinics at universities and other institutions. However, there can be no semblance of a double standard for judging the quality of intramural research versus that funded under grants or contracts. To that end, we have developed a rigorous, standardized review process for the science performed in our own laboratories that is comparable to the NIH grant peer review system. This publication describes the process and should ensure that all NCI staff members are thoroughly versed on our intramural review process and apply it consistently. Not all institutions understand, or need to understand, the governance of science at other institutions. In the case of the NCI, the close association of the funding of scientific extramural programs to the intramural facilities makes it necessary for our colleagues everywhere to have a clear understanding of how we allocate funds for and review our intramural programs. Toward that end this publication will be made available to the outside community in line with the Institute's continuing commitment to doing business in an open, accountable manner.

Vincent T. DeVita, Jr., M.D.
Director
National Cancer Institute

I. Introduction

This document is a staff policy guide designed to ensure a consistent approach to the peer review of intramural research programs throughout the National Cancer Institute (NCI); the document also provides information on the intramural review and evaluation process for those outside the Institute who are interested in or need to know about the process. Generally, informational material is presented in the first part of the document. While each operating division in the NCI uses slightly different procedures for its intramural review process, every division follows the policy guidelines explained in this document.

II. The NCI Intramural Review Process

The National Cancer Institute conducts intramural cancer research programs in its Bethesda, Maryland, laboratories at the National Institutes of Health (NIH), at other satellite locations in the Washington, D.C. metropolitan area, and at the Frederick Cancer Research Facility in Frederick, Maryland. These programs are operated by four NCI Divisions: the Division of Cancer Biology and Diagnosis (DCBD), the Division of Cancer Cause and Prevention (DCCP), the Division of Cancer Treatment (DCT), and the Division of Resources, Centers, and Community Activities (DRCCA).

The intramural research programs are qualitatively and quantitatively evaluated in each division by a Board of Scientific Counselors, a group of non-government advisors who review the research and make critical peer judgments. Each of the four Boards supervises, arranges, and conducts regularly scheduled site visits to each NCI intramural laboratory and branch every 3 to 4 years. Board members review and evaluate not only individual scientific projects but also the overall direction of the intramural research being conducted by the various divisions. Recommendations of the Boards may range from suggested shifts in allocations of financial and personnel resources to changes in program emphasis or even major organizational changes. These recommendations are highly instrumental in shaping the intramural programs of the NCI.

Exhibit I depicts the process from the initial determination of a site visit schedule to the follow up report from the division to its Board.

A. Board of Scientific Counselors

In describing the evaluation of the quality of research being conducted by the NCI intramural programs it is necessary to appreciate the central and pivotal role that the Boards of Scientific Counselors play in the entire process. The NCI is unique among the NIH institutes in having multiple boards of scientific counselors (one for each operating division). These boards are constituted to reflect the mission and composition of the respective programs of each division and have between 15 and 20 members. The law requires that the chairman and at least 75 percent of Board members be non-Federal employees. In practice, virtually all Board members are drawn from outside the government, particularly from academic and other non-profit institutions engaged in biomedical research. Appointees to the Boards of Scientific Counselors are carefully selected in accordance with Departmental policy to ensure that members have the highest scientific qualifications and that each Board has an appropriate balance of expertise, institutional, geographic and minority representation. Appointments to the Boards range from 2 to 4 years and appointment terms are staggered so that one-fourth of the membership of a group is replaced each year. This staggered rotation assures continuity of the Boards from one year to the next, while permitting representation of varying points of view.

1. Responsibilities of the Boards of Scientific Counselors

The Boards of Scientific Counselors serve several functions within the NCI. Each Board:

—conducts an annual review of the entire divisional budget at the beginning of each fiscal year;

—approves the concept of each new contract and contract recompetition proposed by the division for the fiscal year, as well as monies to be spent for grants which utilize the Request for Application (RFA)* funding mechanism;

—provides advice on all problems that have arisen which would have impact on the spending plans of the division;

—provides advice on unusual management issues that confront each division;

—provides peer review of the intramural programs through a process of site visiting. It is this responsibility which is addressed in detail in this document.

2. Role of the Boards of Scientific Counselors in the Evaluation of Intramural Research Programs

The Directors of DCBD, DCCP, DCT, and DRCCA rely heavily upon the advice of their Boards of Scientific Counselors in evaluating the effectiveness and quality of their intramural research programs. This is particularly appropriate because each Board also has an overview of its division's extramural programs. Thus, they are in a position to judge the balance of resources between intramural and extramural programs.

The Boards are concerned not only with individual research projects conducted by each laboratory, branch and section, but also with the overall scientific direction of the programs being conducted by each division. Division Directors depend upon their Boards' advice when making key decisions on such important issues as: major reallocations of personnel or financial support; establishment or abolishment of new organizational units or program activities; significant expansion or curtailment of existing activities; and a wide array of other issues dealing with the quality and efficacy of divisional programs. For example:

- A Board of Scientific Counselors' recommendation was highly instrumental in the decision to establish DCT's Biological Response Modifiers Program.

- The DCCP Board conducted—with some assistance from ad hoc consultants—a cost-accounting study on an isolated aspect of the Field Studies and Statistics Program, to determine if certain patient follow up studies were being conducted in a cost-effective manner.

B. Pre-Site Visit Preparation

1. Schedule of Intramural Program Reviews

The intramural research evaluation process begins with a schedule of site visit reviews for each of the laboratories and branches to be evaluated by a Board of Scientific Counselors.

*The RFA is a technique used to stimulate or discern investigator interest in certain scientific areas.

This schedule is determined jointly by the Director of each division and the Chairman of the Board of Scientific Counselors in consultation with Board members. The Boards consult with divisional officials primarily on matters such as the timing of the visit. Otherwise, the Boards themselves virtually control the entire process. The review process is continuous. The NCI has 41 intramural laboratories/branches and requires an in-depth review of every unit during each 3 to 4 year cycle. When the schedule is completed the entire process is begun again. This is consistent with the usual period of time in which a grant application is renewed and re-evaluated through the Study Section peer review system. Such a time frame allows staff to implement recommendations made by the Board during the previous site visit and time for sufficient scientific progress to be accomplished before another evaluation by the Board.

2. Selection of Site Visit Team

Once a schedule has been determined and an approximate date for the site visit has been selected, the Chairman of the Board of Scientific Counselors then selects a member of the Board to serve as site visit Chairman, and usually several other Board members with particularly relevant scientific background to serve on the team. The Chairman of the site visit team chooses ad hoc consultants with highly specialized research expertise when they are needed on a case basis and when that expertise is not available from the Board's membership. This approach expands the research experience base of the Board and ensures a multidisciplinary team that is fully capable of reviewing in detail all of the science to be evaluated. Although the Division Director and a few other key divisional staff members are sometimes consulted for their opinions on the need for ad hoc expertise on the site visit team, the Chairman of the team exercises absolute authority in the final selection of ad hoc advisors for the visit.

C. The Intramural Site Visit

Usually, site visits require from 1½ to 3 days for the evaluations, depending upon the complexity and size of the laboratory/branch and the science to be reviewed. Typically, an evening session precedes the first business day of the site visit, allowing the visitors to convene as a group to discuss their first overall impressions of the background material and, as a group, to clarify areas of concern and questions regarding science and/or resources. The Division Director and/or the Associate Division Director whose Program falls within the purview of the site visit participate in this session.

The first day of the site visit usually begins with a formal orientation by the Division Director, relevant Program Associate Director, and Laboratory/Branch Chief. Attempts are made to familiarize the site visitors with the relative size and complexity of the laboratory/branch in comparison with others in the division, and to describe its mission within the context of the overall mission of the division. After this general orientation, the senior investigators of the laboratory/branch give oral presentations to the site visit team on the highlights of their individual research projects. In many

cases reviewers also interview each senior investigator privately, at the reviewer's option, in order to gain an in-depth perspective of certain projects.

D. Site Visit Report

At the end of the site visit presentations, the visitors again convene as a group in executive session to discuss and critique the science, and based on that, the allocation of resources. The Division Director is present at this executive session and participates in the discussions. A consolidated report is prepared by the site visit team and is sent to the Division Director and each Board member at least 1 month before the next meeting of the Board. The site visit report is then discussed and modified at the next full meeting of the Board in closed session, and then declared by majority vote to be the Board's recommendations for consideration by the Division Director.

III. Important Policy Requirements in The Intramural Review Process

In order to assure a consistent approach to the peer review of intramural research programs throughout NCI, certain aspects of the process have been established as standardized requirements throughout the Institute. These requirements are covered in the material that follows.

A. Specific Intramural Issues Addressed by the Boards of Scientific Counselors

When conducting reviews of intramural programs each Board is asked:

—to determine the relevance of the science of the NCI laboratories/branches to the mission of the division;

—to determine the necessity and/or desirability of ongoing intramural efforts in specific areas covered by the NCI laboratories/branches;

—to assess whether the quality of science is sufficient to warrant the current level of resource support of the organizational units, projects, and senior investigators devoted to these areas;

—to identify additional areas of science which should be addressed by NCI intramural laboratories/branches or programs based on evolving state-of-the-art developments in cancer research as a whole.

B. Advance Preparation by the Site Visitors

At least 1 month before the site visit is to take place the laboratory/branch submits a package of background review materials for the reviewers to read before the actual scientific presentations are made during the site visit. This written material is similar to that provided by a program project (PO1) grant applicant and describes the past accomplishments of the laboratory/branch, its current activities, and its future plans. It addresses not only science but also resources including space, personnel, and funding. These packages include:

—a description of the division's organization and functions by laboratory/branch and section;

—information describing current and future research activities by section and by project;

—a list of all personnel including *Curriculum Vitae* of all professional employees;

—a detailed compilation of resources for each laboratory/branch (broken down to the section level where applicable), which includes:

(a) space data: square footage, type of space, and floor plans;

(b) personnel resources: the number and types of personnel in a given laboratory;

(c) operating costs: expenditures by major direct cost category such as personnel, supplies, equipment, travel, etc., and information on indirect cost.

While the organization of and format for this material may vary slightly from division to division, each organization must provide the same baseline information in order to allow the members of the Boards and the site visit teams to compare one component with another, as well as to correlate this information with that derived from their experience in reviewing grant and contract applications.

C. Composition of the Site Visit Report

Although the style and format of the site visit reports may vary slightly because of the preferences of each Board, every report will have these common components:

- a descriptive narrative that includes:

  —a review of past, current, and proposed future research activities;

  —a critique of each research project and senior investigator;

  —a critical assessment of the resources allocated to the organization and projects under review;

- a qualitative judgment on the merits of each research project;

- observations on the relevance and direction of the research under review, vis-a-vis the mission of the laboratory/branch, its parent division, and current cancer research developments outside of the NCI;

- a summary of the Board's major comments and observations. This summary is to include distinct, specific recommendations, for action by the Division Director, that flow from the Board's judgmental evaluation of the items cited immediately above. These recommendations obviously will vary from one laboratory/branch to another. Typically, they encompass things such as redirection, intensification or de-emphasis, as appropriate, for specifically identified segments of the research efforts that were reviewed; reallocations of resources; or, possibly reorganization steps that might foster better collaboration between certain investigators whose research efforts are becoming highly related.

D. NCI Follow up on Board of Scientific Counselors Recommendations

After the site visit report is adopted by the Board it is forwarded to the Division Director for consideration and implementation of the recommendations. The Division Director will meet with the appropriate Program Associate Director to discuss the site visit report and the recommendations it contains. The Associate Director then meets with the responsible Laboratory/Branch Chief for continued discussion and planning of implementation actions. The Laboratory/Branch Chief ordinarily has the primary responsibility to see that any changes in research are operationally implemented, with the actual implementation usually done through a section chief(s). The Division Director and the Associate Director for the Program involved are ultimately responsible to ensure that the changes are made. This responsibility flows through the typical chain-of-command pattern that is common to the intramural programs of all divisions. Resource reallocations involve the Laboratory/Branch Chief, but most major action steps must be taken at higher levels to coincide with the Institute's resource management process.

E. Division Report to Board of Scientific Counselors on Implementation of Site Visit Recommendations

Approximately 1 year following receipt of the site visit report, a follow up report is presented by the Associate Program Director or Division

Director to the Board. This report demonstrates how the division has responded to the Board's criticisms and recommendations. It specifies:

—the recommendations that were accepted and the steps that have been taken to implement them;

—any remaining implementation actions and a proposed time frame for accomplishing them;

—any recommendations that the division may have disagreed with—or considered impracticable—and the reasons why.

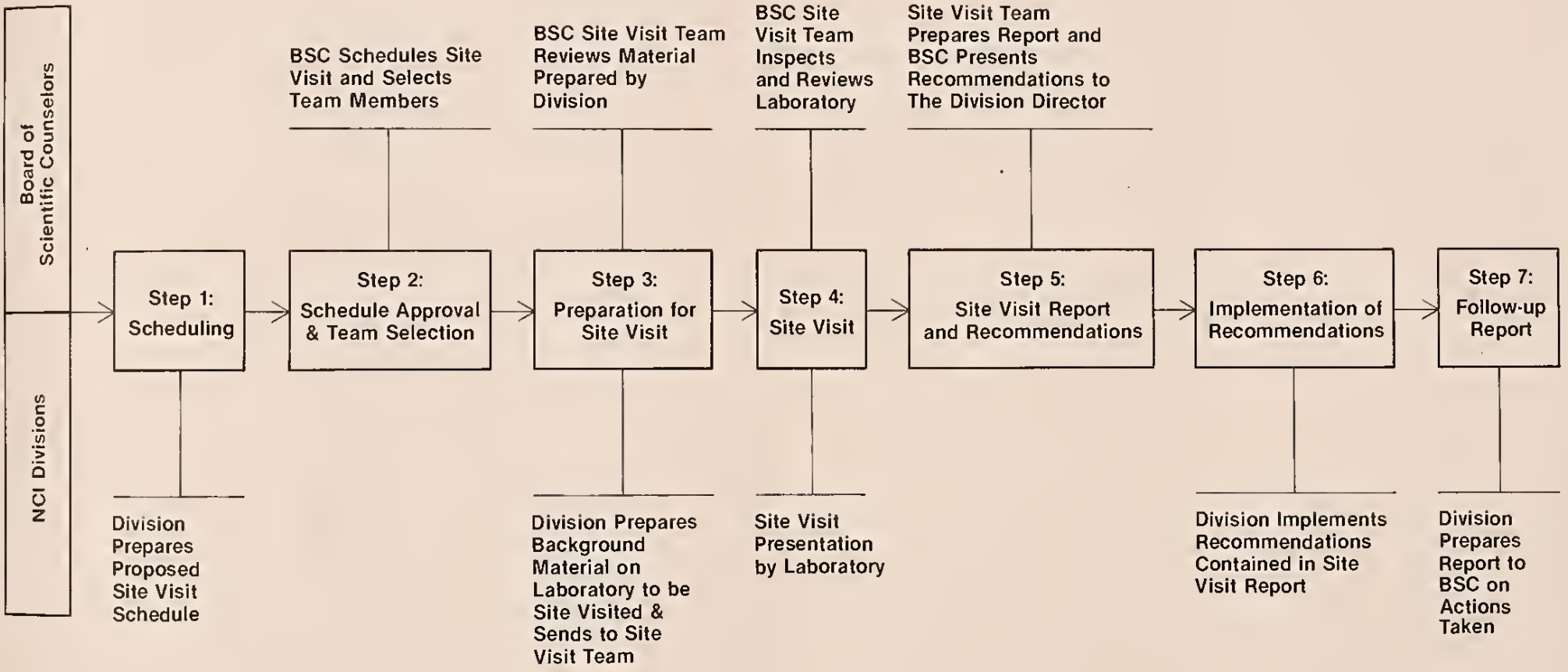
In cases where the Board recommends substantial changes in the operations and/or organization of certain intramural laboratories or branches, it is not always possible to meaningfully implement the recommendations within 1 year. In these cases the division will make a second, follow up report to the Board, usually within 18 months after the initial discussion of the site visit report.

Three to four years later, the entire process begins again for the same Laboratory/Branch, and the previous site visit results are incorporated as one of the considerations in that next review. Also, some of the reviewers from the previous site visit team will be used again for continuity. If necessary, former board members whose terms have expired will be used as ad hoc reviewers on the subsequent site visit.

☆ U. S. GOVERNMENT PRINTING OFFICE : 1982—522-025/5541

Exhibit I

NCI Intramural Review Process



National Cancer Institute